IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ex rel. JOHN UNDERWOOD, et al., Plaintiffs,	:	
v.	:	**CIVIL ACTION NO. 03-3983**
GENENTECH, INC., et al., Defendants.	:	

ORDER

AND NOW, this 15th day of July, 2010, upon consideration of Defendant Genentech's Motion to Dismiss the Second Amended Complaint (Doc. No. 86), Relator's Response (Doc. No. 91), Genentech's Reply (Doc. No. 93), the United States' Statement of Interest (Doc. No. 94), and Genentech's Response (Doc. No. 95), it is **ORDERED** that the Motion (Doc. No. 86) is **DENIED** as follows:

I. BACKGROUND

1. Defendant Genentech, Inc. is a California-based biotechnology company. In 2003, Relator John Underwood (then a Genentech employee) informed the Department of Justice that Genentech was defrauding Medicare and Medicaid through an "off-label" marketing and kickback scheme. *(Doc. No. 63, Ex. A ¶¶ 10, 14.)* On July 3, 2003, Relator filed under seal a *qui tam* Complaint, alleging violations of the False Claims Act through underlying violations of the Medicare and Medicaid Fraud and Abuse Act. See 31 U.S.C. §§ 3729 *et seq.*; 42 U.S.C. §§ 1320 *et seq.* He filed his First Amended Complaint under seal on November 8, 2005. *(Doc. No. 15.)*

For the next six years, the DOJ investigated Relator's allegations, obtaining some seven million documents from other federal agencies and from Genentech itself. On September 25, 2009, the United States filed a Notice of Election to Decline Intervention. *(Doc. No. 29.)* To help him decide whether to proceed with this action, Relator subpoenaed the seven million documents from the DOJ. See Fed. R. Civ. P. 45; Doc. No. 46. Although the DOJ provided Relator with documents it had obtained from other federal agencies, it declined, absent court order, to provide those documents it had obtained directly from Genentech. *(Doc. No. 48.)* When the DOJ notified Genentech of the subpoena, the Company moved for protective relief. *(Doc. No. 45.)* After a hearing on December 17, 2009, I denied protective relief and ordered the DOJ to comply with Relator's third party subpoena. *(Doc. No. 54.)*

2. Relator filed a Motion for Leave to File Second Amended Complaint on April 15, 2010. *(Doc. No. 63.)* On April 23, 2010, Genentech filed a "Partial Opposition to Relator's Motion to Amend." *(Doc. No. 68.)* The Company suggested that the Relator should be allowed "some latitude to amend his complaint based on changes in his legal theories or his own recollections." *(Doc. No. 68 at 3.)* Genentech vigorously objected, however, to any amendments based on "documents Genentech produced to the Government." *(Id. at 5.)* Genentech found especially objectionable " numerous references [in the proposed amendments] to particular Genentech sales figures, presentations, and emails." Indeed, Genentech provided me with a redlined comparison of the First and Second Amended Complaints, identifying both the challenged amendments and the Company documents upon which they were "impermissibly" based. *(Id., Ex. A.)*

3. Before ruling on Relator's Motion to Amend, I ordered the Parties to submit memoranda addressing whether the First Amended Complaint was adequate under Rule 9(b). *(Doc. No. 72.)* Genentech instead moved to dismiss the First Amended Complaint, arguing that it did not pass muster under Rule 9(b). *(Doc. No. 73.)*

4. On June 2, 2010, I issued a Memorandum and Order denying Genentech's Motion to Dismiss and, in the alternative, allowing Relator to amend. I first concluded that the Complaint

Relator sought to amend – which included detailed allegations of Genentech's fraudulent scheme – was adequate under Rule 9(b). *(Doc. No. 78.)* I then concluded in the alternative that regardless of whether that Complaint was adequately pled, Relator could amend with discovery he had obtained from the DOJ. *(Id.)* In my discussion of this second issue, I noted what was absolutely clear from Genentech's filings: that the Company objected only to those amendments the Relator had based on documents that the DOJ had obtained from Genentech. I further noted that although the law usually does not allow a *qui tam* relator to save an inadequately pled complaint by adding amendments based on discovery obtained from the defendant, there is no authority barring such amendments based on discovery obtained from an agency of the federal Government. See United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232 (1st Cir. 2004) ("In many of these cases, the information needed to fill the gaps of an inadequately pleaded complaint will be in the government's hands."); see also United States ex rel. Russell v. Epic Healthcare Mgmt. Group, 193 F.3d 304, 308 (5th Cir. 1999) (refusing the relator's request to take discovery from the defendant to bolster his complaint "because documents containing the requisite information were possessed by other entities, such as the Healthcare Financing Administration [now the Centers for Medicare and Medicaid Services])." Accordingly, I denied Genentech's Motion to Dismiss *(Doc. No. 73)* and, in the alternative, granted Relator's Motion to Amend *(Doc. No. 63)*. I denied Genentech's Motion for Reconsideration on June 29, 2010. *(Doc. No. 89.)*

5. On June 23, 2010, Genentech filed a motion seeking certification for immediate interlocutory appeal of my June 2nd Memorandum and Order. *(Doc. No. 85.)* Genentech sought Third Circuit review of the following questions: (1) "Whether, to satisfy Rule 9(b) of the Federal Rules of Civil Procedure, a FCA relator alleging that the defendant caused a third party to submit false or fraudulent claims must allege with particularity a single false or fraudulent claim or whether

such a relator can satisfy 9(b) in some other way"; and (2) "[W]hether a FCA relator may use discovery to amend a deficient complaint." *(Doc. No. 85 at 5.)* I denied that Motion on July 12, 2010. *(Doc. No. 96.)*

6. Genentech filed the instant Motion on June 23, 2010, arguing that the Second Amended Complaint does not meet Rule 9(b)'s heightened pleading requirement. *(Doc. No. 86 at 26.)* Genentech also argues that: (1) Count One should be dismissed for failure to identify a legally cognizable false or fraudulent claim that was submitted to the Government; and (2) Count Two should be dismissed because it does not establish that Genentech violated the federal Anti-Kickback Statute, a section of the Medicare and Medicaid Fraud and Abuse Act. *(Doc. No. 86 at 8,22.)* See also 42 U.S.C. §§ 1320 *et seq*. Relator filed a Response in opposition to the Motion on July 2, 2010 *(Doc. No. 91)*, and, on July 6, 2010, Genentech filed a Reply. On July 6, 2010, the United States submitted a Statement of Interest in response to Genentech's Motion, arguing that Genentech "has misstated the law on several aspects of the False Claims Act." *(Doc. No. 95 at 2.)* Genentech filed a response to the Statement of Interest on July 7, 2010. *(Doc. No. 95.)*

II. LEGAL STANDARDS

7. In deciding a motion to dismiss for failure to state a claim upon which relief may be granted, I must accept as true the non-moving party's factual allegations and make all reasonable inferences in the non-moving party's favor. Fed. R. Civ. P. 12(b)(6); In re Rockefeller Ctr. Props., Inc., 311 F.3d 198, 215 (3d Cir. 2002). The burden is on the moving party to show that the non-moving party has failed to allege facts sufficiently detailed to "raise a right to relief above the speculative level." Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955, 1964-65, 1974 (2007); Phillips v. County of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008). "The inquiry is not whether [the non-moving party] will ultimately prevail on the merits, but whether they should be afforded an

opportunity to offer evidence in support of their claims." In re Rockefeller, 311 F.3d at 215.

8. Rule 9(b) provides that "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). This heightened pleading standard is intended "to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984). The Third Circuit has cautioned against overemphasizing the specificity requirement:

> Under Fed. R. Civ. P. 9(b), plaintiffs must plead with particularity the circumstances of the alleged fraud. They need not, however, plead the date, place or time of the fraud, so long as they use an alternative means of injecting precision and some measure of substantiation into their allegations of fraud.

Rolo v. City Investing Co. Liquidating Trust, 155 F.3d 644, 658 (3d Cir. 1998) (internal citations omitted). Although the Third Circuit has suggested that a heightened standard applies to False Claims Act complaints, it has not yet defined that standard. See United States ex rel. St. John LaCorte v. Smithkline Beecham Clinical Lab., 149 F.3d 227, 234 (3d Cir. 1998).

III. DISCUSSION

9. In my June 2nd Memorandum, I ruled that the First Amended Complaint was sufficient to meet Rule 9(b)'s heightened pleading standards. *(Doc. No. 78 at 15.)* As I explained at length in that decision, Relator was not obligated to identify a specific false claim because he had alleged that Genentech corruptly induced *others* to submit false claims to the Government. In such circumstances, it would be inappropriate to require at the pleading stage the identification of a false claim. *(Id. at 14.)* I noted that although Relator was not obligated to plead

a particular false claim, he was obligated to "use an alternative means of injecting precision and some measure of substantiation into [his] allegations of fraud," thus placing Genentech "on notice of the precise misconduct with which [it is] charged," and safeguarding "against spurious charges of immoral and fraudulent behaviors." *(Id. (citing Rolo, 155 F.3d at 658; Seville, 742 F.3d at 791)).* I noted that Relator had alleged in detail Genentech's scheme to bribe doctors and other health care providers to write thousands of Rituxan prescriptions for non-approved uses. *(Id. at 14.)* Relator also alleged that many thousands of prescriptions were written for Medicare/Medicaid patients, resulting in the presentation of many millions of dollars in false claims to the Government. *(Id. (citing Doc. No. 15 at ¶¶ 23-34)).* As I stated, "there is no mystery or ambiguity to these allegations. Either Genentech lavishly bribed doctors to prescribe Rituxan for off-label use or it did not. Relator's allegations are sufficiently specific both to inform Genentech of the 'precise misconduct' charged, and to make it unlikely that Relator has commenced this action in bad faith." *(Id. at 14-15.)*

10. The First and Second Amended Complaints include the same core allegations: that Genentech carried out a fraudulent scheme to profit from off-label Rituxan prescriptions written for Medicare and Medicaid patients. Both pleadings set out the two ways that Genentech engineered this scheme: (1) pressuring its sales staff illegally to market off-label uses for Rituxan prescriptions; and (2) paying illegal kickbacks – tropical vacations or honoraria – to induce and reward physicians who prescribed off-label Rituxan. The Second Amended Complaint includes only two Counts, both untitled, in which Relator consolidates and refines the allegations that were in the seven-count First Amended Complaint. In the Second Amended Complaint, Relator also adds new factual allegations, purportedly based on internal Genentech documents, and sets out the Company's alleged efforts to promote off-label Rituxan use, including the bribes it paid to physicians in greater detail.

Accordingly, because in the Second Amended Complaint Relator merely adds detail to the First Amended Complaint – a pleading I have already deemed adequate under Rule 9(b) – the Second Amended Complaint certainly meets the Rule's particularity requirements.

11. In arguing that Count I of the Second Amended Complaint does not include a legally cognizable false claim, Genentech again raises a claim I have rejected. Relator alleges that between 2000 and 2005, Genentech's off-label Rituxan marketing "caused tens of thousands of fraudulent claims to be submitted to the Medicare and Medicaid programs." *(Doc. No. 80 ¶¶ 53-55.)* As I explained in my June 2nd Memorandum, again in my June 29th Order, and yet again in my July 12th Order, Relator is not required to plead an actual false claim. The Second Amended Complaint, like the First Amended Complaint, includes allegations that Genentech created an "off-label" marketing scheme in which false claims were submitted not by the Company, but by third parties. As I have repeatedly explained, these allegations are adequate at the pleading stage. See 31 U.S.C. § 3729(a)(1) (any person who "presents, or *causes to be presented*, a false or fraudulent claim for payment . . ., is liable to the United States government for a civil penalty") (emphasis supplied); United States ex rel. Grubbs v. Ravikumar Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009) ("production of actual documentation with the complaint [for a motion to dismiss would require] a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates").

Genentech also contends that Relator fails to plead that the Company's behavior: (1) was fraudulent, (2) led to the submission of any false claims, or (3) was material to any payment decision of the Government. Again, I disagree. Genentech's alleged actions were certainly fraudulent. Moreover, although some courts have held that FCA claims are subject to a judicially-created materiality requirement, the Third Circuit has explicitly declined to decide this issue. See United States ex rel. Cantekin v. Univ. of Pittsburgh, 192 F.3d 402, 415 (3d Cir. 1999) ("In any event, we need not decide whether there is a materiality requirement under the False Claims Act, because even if there is, we think it is clear that Bluestone's failure to disclose his industry funding would readily qualify as material."). In any event, the Court noted that materiality may be satisfied if a reasonable person would know a governmental agency would consider the information important to its payment decision. Id. In its Statement of Interest, the Government emphasizes that "the fact that a claim is for an off-label, non-reimbursable use is material to the Government's decision to pay that claim." *(Doc. No. 94 at 7.)* I agree with the Government. Accordingly, if materiality is indeed required, Relator's allegations are sufficient to meet that requirement.

12. Genentech's last argument – the only argument that is not a regurgitation of contentions that I have repeatedly rejected – is that I should dismiss Count Two of the Second Amended Complaint because it fails to establish that the Company violated the federal Anti-Kickback Statute, and that any resulting claims for reimbursement were not necessarily false claims. *(Doc. No. 86 at 22.)* See also 42 U.S.C. §§ 1320 *et seq.*

Genentech has misstated the law. Compliance with the Anti-Kickback Statute is a condition of payment under the Medicare and Medicaid programs. See, e.g., United States v. Rogan, 517 F.3d 449, 452-53 (7th Cir. 2008). The Third Circuit has held that "[f]alsely certifying compliance with the Stark or Anti-Kickback Acts in connection with a claim submitted to a federally funded insurance program is actionable under the FCA." United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 94 (3d Cir. 2009). In addition, as the Government notes in its Statement of Interest, the Anti-Kickback Statute was recently amended to clarify "that all claims for services that were tainted by the payment of a kickbacks are false claims within the meaning of the FCA, regardless of what entity ultimately submitted the claims for payment." *(Doc. No. 94 at 11-12.)* See also Patient Protection and Affordable Care Act, § 6402(f), 42 U.S.C. § 1320a-7b(g).

Assuming Relator's allegations are true, as I must at this stage of the litigation, Genentech violated the Anti-Kickback Statute by bribing doctors to write off-label Rituxan prescriptions. The FCA prohibits "causing" the submission of false claims. Claims tainted by kickbacks are "false" within the meaning of the FCA. Accordingly, Count Two includes a cognizable FCA claim.

IV. CONCLUSION

For these reasons, Genentech's Motion to Dismiss is denied.

AND IT IS SO ORDERED.

/s/ Paul S. Diamond

Paul S. Diamond, J.